



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone 510-337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 29-52421

November 4, 1996

Tony F. Diniz
9558 Columbus Ave.
Hilmar, California 95324

WARNING LETTER

Dear Mr. Diniz:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your firm on August 16 and 19, 1996 by Food and Drug Administration (FDA) Investigator Christopher J. Lee, have revealed serious violations of the Federal Food, Drug, and Cosmetic Act as follows:

A food is adulterated under Section 402(a)(2)(D) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512 of the Act. On June 19, 1996, you consigned a dairy cow (identified by USDA laboratory report number 206099) for slaughter as human food. This cow was delivered for introduction into interstate commerce by your firm and was adulterated by the presence of illegal antibiotic drug residues. USDA analysis of tissues from this cow revealed the presence of oxytetracycline in the kidney at 1.90 parts per million (ppm). The tolerance level for oxytetracycline in the edible tissues of cattle has been established at 0.1 ppm.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that

medicated animals bearing possibly harmful drug residues are likely to enter the food supply. For example, our investigator noted the following:

1. You lack an adequate system for determining the medication status of animals you offer for slaughter.
2. You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drug.
3. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling.
4. You lack an adequate system for determining that quantities of drugs are being accounted for to prevent the possible overdosing of animals.

The drug Panmycin 500 brand oxytetracycline that your establishment uses on lactating dairy cows is adulterated within the meaning of Section 501(a)(5) of the Act, in that it is a new animal drug within the meaning of Section 201(w) and is unsafe within the meaning of Section 512(a)(1)(B) of the Act since it is not being used in conformance with prescribed labeling. Your veterinarian prescribed a twenty day withdrawal period prior to slaughter for food use. Failure to adhere to the prescribed withdrawal time is likely the cause of the illegal residues in the cow you sold for food use.

You are using the drug penicillin G procaine in a manner not in conformance with its approved labeling. Penicillin G procaine labeling warns against using more than one milliliter (ml) per 100 pounds of body weight and no more than 10 mls per injection site. Your practice of administering 30 to 40 mls per cow and splitting this amount into two equal dosages of 15 to 20 mls per site results in dosages in excess of that allowed by the labeling. This overdosing presents a possibility that illegal residues will occur. Also, your practice of administering penicillin G procaine at dosages of 10 to 12 mls intramammary in your cows is an unapproved use for which safety and efficacy have not been established.

Failure to comply with the label instructions on the drugs you use to treat your dairy cows makes the drugs unsafe for use.

We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act.

Antonio Diniz
Hilmar, CA

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Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal for sale to a slaughter facility where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

This is not intended to be an all-inclusive list of violations. It is your responsibility to ensure that all requirements of the Act and regulations are being met. Failure to achieve prompt corrective action may result in enforcement action without further notice, including seizure and/or injunction.

Within fifteen (15) days of the receipt of this letter, notify this office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should include copies of any available documentation demonstrating that corrections have been made. Please direct your reply to John M. Reves, Compliance Officer.

Sincerely yours,

Patricia C. Ziobro

Patricia C. Ziobro
District Director
San Francisco District

cc:

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